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*Admitted only in Maryland *Admitted only in Virginia •Practice Limited to Federal Agencies

August 31, 2004

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Art Unit 1632

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Re:

U.S. Utility Patent Application

Application No. 10/658,688; Filed: September 10, 2003

Codon-Optimized Polynucleotide-Based Vaccines Against Bacillus

anthracis Infection

Inventor: Our Ref:

Gary G. HERMANSON 1530.0460002/EJH/J-H

Sir:

Transmitted herewith for appropriate action are the following documents:

- 1. Information Disclosure Statement;
- 2. Form PTO-1449, 28 pages, listing 147 documents;
- 3. One (1) copy of cited documents AL1-AN4, and AR1-AR28 (100 documents);
- 4. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

> The PTO did not receive the following listed Item(s) CA2, 202 322

Sterne, Kessler, Goldstein & Fox P.L.C.: 1100 New York Avenue, NW: Washington, DC 20005: 202.371.2600 f 202.371.2540: www.skgf.com

Commissioner for Patents August 31, 2004 Page 2

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

Elizabeth J. Haanes, Ph.D. Attorney for Applicant

Registration No. 42,613

EJH/J-H/tis

298225v1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HERMANSON

Appl. No.: 10/658,688

Filed: September 10, 2003

For: Codon-Optimized Polynucleotide-Based Vaccines Against *Bacillus*

anthracis Infection

Confirmation No.: 3461

Art Unit: 1632

Examiner: Baskar, P.

Atty. Docket: 1530.0460002/EJH/J-H

Information Disclosure Statement under 37 C.F.R. § 1.97(b)

Commissioner for Patents PO Box 1450 Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98. Copies of U.S. patents and patent application publications cited on the attached Form PTO-1449 are not submitted in accordance with 1276 OG 55 because this application was filed after June 30, 2003. Copies of documents AL1 to AN4 and AR1 to AR28 are provided.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following discussion of the relevance of the non-English language documents **AL1-AN1** and **AN3** cited on Form PTO 1449:

Document AL1 is in a foreign language. An English language abstract of document AL1 is attached as document AR27.

Document AM1 is in a foreign language. An English language abstract of document AM1 is attached as document AR27.

Document AN1 is in a foreign language. An English language abstract of document AN1 is attached as document AR27.

Document AN3 is in a foreign language. An English language abstract of document AN3 is attached as document AS27.

The Examiner's attention is directed to the following copending applications:

- U.S. Application No. 09/839,574, inventors Manthorpe *et al.*, filed April 23, 2001, now published as U.S. Published Application No. 2002/0019358 (Document **AJ3**);
- U.S. Application No. 10/725,009, inventor Geall, filed December 2, 2003, now published as U.S. Published Application No. 2004/0157789 (Document AI4);
- U.S. Application No. 10/391,216, inventor Wheeler, C.J., filed March 19, 2003, now published as U.S. Published Application No. 2003/0191082 (Document AC5);
- U.S. Application No. 10/719,978, inventors Budahazi *et al.*, filed November 24, 2003, now published as U.S. Published Application No. 2004/0157244 (Document **AA5**);
- U.S. Application No. 10/725,015, inventors Geall *et al.*, filed December 2, 2003, now published as U.S. Published Application No. 2004/0162256 (Document **AB5**);
- U.S. Application No. 10/387,525, inventor Felgner *et al.*, filed March 14, 2003, now published as U.S. Publication Application No. 2004/0023911 (Document **AJ4**);
- U.S. Application No. 10/202,858, inventor Felgner et al., filed July 26, 2002, now published as U.S. Publication Application No. 2003/0032615 (Document AK4);

U.S. Application No. 10/748,853 (unpublished), inventor Wheeler, C.J., filed December 30, 2003, a copy of which is attached as Document AT27;

U.S. Application No. 08/486,533 (unpublished), inventor Felgner, *et al.*, filed June 07, 1995, a copy of which is attached as Document **AR28**; and

U.S. Application No. 09/937,604, inventor Wheeler, C.J., filed September 26, 2001 (National Phase of PCT/US00/08282, published as WO 00/57917, attached as Document AM3);

which are directed to related technical subject matter. The identification of these U.S. Patent Applications is not to be construed as a waiver if secrecy as to those applications now or upon issuance of the present application as a patent. The Examiner is respectfully requested to consider the cited applications and the art cited therein during examination.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicant has listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicant reserves the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. No statement or fee is required.

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

lizabeth J. Haanes, Ph.D.

Attorney for Applicant

Registration No. 42,613

Date: (

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291746

Page 1 of 28 APPLICATION NO. ATTY. DOCKET NO. 10/658,688 1530.0460002/EJH/JAH FQFM PTO-1449 FIRST NAMED INVENTOR Hermanson, G.G. SISCLOSURE STATEMENT ART UNIT FILING DATE September 10, 2003 1632 **U.S. PATENT DOCUMENTS** DOCUMENT **EXAMINER** SUB-CLASS DATE NAME **CLASS** FILING DATE INITIAL NUMBER 4,683,195 Mullis et al. 02/07/1986 AA1 07/28/1987 AB1 5,264,618 11/23/1993 Felgner et al. 04/16/1991 Makoff et al. 11/27/1990 AC₁ 5,389,540 02/14/1995 AD1 5,443,966 08/22/1995 Fairweather et al. 08/23/1993 AE1 5,459,127 10/17/1995 Felgner et al. 09/16/1993 AF1 5.571,694 11/05/1996 Makoff et al. 07/25/1994 03/18/1994 AG1 5,580,859 12/03/1996 Felgner et al. 01/07/1997 02/12/1993 AH1 5,591,631 Leppla et al. 07/01/1997 Robinson et al. 01/27/1993 AI1 5,643,578 5,677,274 10/14/1997 Leppla et al. 06/25/1993 AJ1 06/07/1995 05/05/1998 Calderwood et al. AK1 5,747,028 **FOREIGN PATENT DOCUMENTS EXAMINER** DOCUMENT INITIAL DATE COUNTRY CLASS SUB-CLASS **TRANSLATION** NUMBER Yes AL1 CA 2,001,508 04/25/1990 Canada No Yes AM1 EP 0 366 550 A1 05/02/1990 Europe No Yes AN1 WO 90/04637 A1 | 05/03/1990 **WIPO** No Yes WO 94/18332 A2 08/18/1994 **WIPO** AO1 No Yes AP1 WO 94/19482 A1 09/01/1994 **WIPO** No OTHER (Including Author, Title, Date, Pertinent Pages, etc.) Agrawal, A., et al., "Impairment of dendritic cells and adaptive immunity by anthrax lethal toxin," Nature 424:329-334, Nature Publishing Group (July 2003) AR 1 Aihara, H. and Miyazaki, J-I., "Gene transfer into muscle by electroporation in vivo," Nat. Biotechnol. 16:867-870, Nature America Publishing (1998) AS 1 Anderson, R., et al., "Immunization of mice with DNA encoding fragment C of tetanus toxin," Vaccine 15:827-829, Elsevier (1997) AΤ 1 DATE CONSIDERED **EXAMINER**

290671_1.DOC SKGF Rev. 12/03/03

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance

and not considered. Include copy of this form with next communication to Applicant.

		Page 2 of 28
	ATTY. DOCKET NO.	APPLICATION NO.
	1530.0460002/EJH/JAH	10/658,688
FORM PTO-1449	FIRST NAMED INVENTOR	
	Hermanson, G.G.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
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EXAMINER		DOCU				0, 400	0110 01 400	511 IN O DATE
INITIAL	AA2	NUMB 5,837,6		DATE 11/17/1998	NAME German et al.	CLASS	SUB-CLASS	93/24/1995
	AAZ	0,037,0	993	11/1//1998	German et al.			03/24/1995
	AB2	5,840,3	312	11/24/1998	Mock et al.			10/19/1994
	AC2	5,861,3	397	01/19/1999	Wheeler			10/03/1996
	AD2	5,994,3	317	11/30/1999	Wheeler			04/09/1996
	AE2	6,004,9	944	12/21/1999	Rothman et al.			10/02/1997
	AF2	6,022,8	374	02/08/2000	Wheeler			12/23/1998
	AG2	6,224,8	370	05/01/2001	Segal			01/15/1998
	AH2	6,267,9	966 B1	B1 07/31/2001	Baillie	-		08/26/1997
	Al2	6,316,0	006 B1	11/13/2001	Worsham et al.			11/23/1994
	AJ2	6,387,6	665 B1	55 B1 05/14/2002 Ivins et al.			03/07/2000	
	AK2	6,379,	966 B2	04/30/2002	Monahan et al.			11/29/1999
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	AL2	wc	98/08952 A1	05/05/1998	WIPO			Yes No
	AM2	2 WC	98/11914 A1	03/26/1998	WIPO			Yes No
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	AP2		00/02591 A1		WIPO			Yes No
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	AR	2	André, S., e Sequence v (1998)	nation with a Sy erican Society fo	nthetic gp120 r Microbiology			
	AS			AM., et al., "A new vehicle for nonviral gene delivery: supercoiled minicircle," Ge 341-1349, Stockton Press (1997)				
	АТ	Davis, H.L., et al., "Direct gene transfer in skeletal muscle: plasmid DNA-based immunizate the hepatitis B virus surface antigen," <i>Vaccine 12</i> :1503-1509, Elsevier Science (1994)						
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

		Page 3 of 28
	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
FORM PTO-1449	FIRST NAMED INVENTOR	
	Hermanson, G.G.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE	ART UNIT
	September 10, 2003	1632

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EXAMINER			UMENT	D.4.TE		0,400	0110 01 400	511 1110 5475
INITIAL	AA3	NUMI 6.586		DATE 07/01/2003	NAME Wheeler	CLASS	SUB-CLASS	03/24/2000
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	AB3	6,632	2,436	10/14/2003	Segal			02/21/2001
	AC3	6,670,332 B1		12/30/2003	Wheeler			06/05/1998
	AD3	6,696	,424 B1	02/24/2004	Wheeler			05/26/2000
	AE3	5,589	,466	12/31/1996	Felgner et al.			01/26/1995
	AF3	6,214	,804 B1	04/10/2001	Felgner et al.			06/07/1995
	AG3	5,703	,055	12/30/1997	Felgner et al.			01/26/1994
	АН3	6,710	,035 B2	03/23/2004	Felgner et al.			12/02/1999
	AI3	2001/	0031264 A1	10/18/2001	Segal			02/21/2001
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 	AK3	2002/0045594 A1	04/18/2002	Volkin et al.			09/12/2001	
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INITIAL		INC	JMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION Yes
	AL3	W	O 00/56282 A1	09/28/2000	WIPO			No.
	AMS	s w	O 00/57917 A2	10/05/2000	WIPO			Yes No
	ANS	w	O 01/19395 A1	03/22/2001	WIPO			Yes X No
	AOS	s w	O 01/34801 A2	05/17/2001	WIPO			Yes No
	AP3	w	O 01/45639 A2		WIPO			Yes No
	OTHER (Including Author, Title, Date, Pertinent Pages, etc.)							
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		Page 4 of 28
	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
FORM PTO-1449	FIRST NAMED INVENTOR Hermanson, G.G.	
INFORMATION DISCLOSURE STATEMENT	FILING DATE September 10, 2003	ART UNIT 1632

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NITIAL	AA4	NUMBE 2002/00	48590 A1	04/25/2002	Klimpel et al.	CLASS	SUB-CLASS	05/09/2001
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	AB4	2002/00	51791 A1	05/02/2002	Galloway et al.			12/21/2000
	AC4	2002/0081317 A1		06/27/2002	Mahan et al.			08/09/2001
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	AG4	2002/01	97272 A1	12/26/2002	Galloway et al.			03/25/2002
	AH4	2003/00	03109 A1	01/02/2003	Galloway et al.			03/25/2002
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	AJ4	2004/00	23911 A1	02/05/2004	Felgner et al.			03/14/2003
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	AL4	woo	2/00844 A2	01/03/2002	WIPO			Ye
	AM4	GB 2	,370,772 A	07/10/2002	Great Britain			Y€ N
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	AR	4	Felgner, P.	L., et al., "Lipofe	ction: A highly efficient, li 13-7417, National Acade	pid-mediated DNA	A-transfection pr	ocedure," <i>Proc.</i>
	AS	4	Gao, X. an Biochem. 3	d Huang, L., "Pot 85:1027-1036, An	tentiation of Cationic Lipo nerican Chemical Societ	osome-Mediated C y (1996)	Sene Delivery by	Polycations,"
	АТ	4	Gordon, V. Furin and t Microbiolog	y Additional Cell	olytic Activation of Bacter Jular Proteases," <i>Infection</i>	rial Toxins by Eukan & Immunity 63:8	aryotic Cells Is F 2-87, American	Performed by Society for
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ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
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	AA5	2004/0157244 A1	08/12/2004	Budahazi et al.			11/24/2003
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	AR	5 Comparison	, R.A., <i>et al.</i> , "Im n of Vaccine For er Institute Press	mune Response to a Hepmulation, Route, and Met (1998)	patitis B DNA Vac thod of Administra	cine in <i>Aotus</i> Mo tion," <i>Molec. Me</i>	onkeys: A ed. 4:109-118,
	AS			n against anthrax toxin by e 17:340-344, Elsevier Sc		a DNA plasmid e	encoding anthrax
	AT	Hammond, Infection &	S.E. and Hanna Immunity 66:237	ı, P.C., "Lethal Factor Act 74-2378, American Societ	tive-Site Mutations ty for Microbiology	Affect Catalytic (1998)	: Activity In Vitro,
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		Page 6 of 28
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	AR	<u>6</u>	Hartikka, J. Muscle," <i>H</i>	, et al., "An Imp uman Gene The	roved Plasmid DNA Expressi er. 7:1205-1217, Mary Ann Lie	on Vector for Debert, Inc. (199	Pirect Injection ir 6)	nto Skeletal	
	AS	<u>6</u>	Hartikka, J., et al., "Electroporation-Facilitated Delivery of Plasmid DNA in Skeletal Muscle: Plasmone Dependence of Muscle Damage and Effect of Poloxamer 188," <i>Molec. Ther. 4</i> :407-415, The Amage Society of Gene Therepy (November 2001)						
	АТ	6	Henderson at the Unive	, D.W., "An App ersity Press (19	aratus for the Study of Airbor 52)	ne Infection," J	l. Hygiene 50:53	-68, Cambridge	
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	AR	Holste, D., et al., "Optimization of Coding Potentials Using Positional Dependence of Nucleotide Frequencies," J. Theor. Biol. 206:525-537, Academic Press (2000)							
	AS	7	Horn, N.A., et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinic Trials," Human Gene Ther. 6:565-573, Mary Ann Leibert, Inc., Publishers (1995)						
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	АТ	8	Kobiler, D., Spores by I (February 2	Passive Immuniz	of Protection of Guinea Pigs ation," <i>Infection & Immunity</i> 70	against Infec 0:544-550, Ai	ition with <i>Bacillu</i> merican Society	s anthracis for Microbiology
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	AR	10	Lindmayer, American D	I., et al., "Develo Diabetes Associa	opment of New Jet Inject ition (1986)	or for Insulin Thera	py," <i>Diabetes C</i>	are 9:294-297,			
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	AS	13	Mock, M. and Fouet, A., "Anthrax," <i>Annu. Rev. Microbiol.</i> 55:647-671, Annual Reviews (January 2001)							
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	AS	<u>15</u>	Pannifer, A.D., et al., "Crystal structure of anthrax lethal factor," <i>Nature 414</i> :229-233, Nature Publishi Group (November 2001)							
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